Human Health Risk Assessment (HHRA) Program
Program Performance Factsheet

Summary of 2007Annual Performance of HHRA[1]

The peer-reviewed products of EPA's Human Health Risk Assessment program are used extensively by EPA programs, regions, and other parties to support activities such as development of regulatory standards and decisions on environmental cleanups. In FY 2007, the program delivered 16 IRIS assessments to interagency or external peer review, and completed 51 new or revised Provisional Peer Reviewed Toxicity Values (PPRTVs). The program was on track to post 4 final IRIS health assessment documents but only 2 final assessment documents were posted by the end of the fiscal year. Two additional final health assessments documents were held up in the OMB clearance process and final comments from OMB were not received until September 28, 2007.

The HHRA program also completed the Lead Air Quality Criteria Document in support of EPA National Ambient Air Quality Standards regulatory decision making, and submitted for Clean Air Scientific Advisory Committee review an external review draft of the *Integrated Science Assessment for Oxides of Nitrogen* and an external review draft of the *Integrated Science Assessment for Oxides of Sulfur.* These integrated science assessments (ISA) for *Oxides of Nitrogen* and *Oxides of Sulfur* are the first documents produced under the new ISA process which reviews, evaluates, and synthesizes the latest relevant available scientific information addressing the nature and extent of health and welfare effects associated with exposure to ambient concentrations of the criteria pollutants. These documents are used by OAR in their review of the NAAQS which serve to protect public health with an adequate margin of safety.

Regarding our methods models and guidance work, the HHRA program met all 3 of its 2007 Annual Performance Measures (APM) (development of 4 additional low-dose extrapolation models, report on central estimates of uncertainty, and technical summary of dermal assessment methods) and completed the one unfinished APM from 2006 (2 final reports on dose-response models for water borne microbes).

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[1]All federal government programs are mandated under the Government Performance Results Act (GPRA) to have program performance goals. These goals must be linked to the mission of the organization and be evaluated annually over a number of years to evaluate progress and some measure of success/impact. The HHRA program has long-term goals (LTGs), annual performance goals (APG's) and annual performance measures (APM's) to meet these mandates. In addition, the program is also evaluated by OMB on regular cycle (approximately every 4 years with mid-cycle progress reports) using the Program Assessment Rating Tool (PART). Selected Annual Performance Measures have been negotiated with OMB for PART Annual Measures and PART Long-Term Measures (See discussion below). The past performance evaluations and future goals factor into the Presidential budget request for program resources in the form of Congressional justification (CJ) language.

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For the PART process a set of annual measures was negotiated with OMB. The following information relates to the PART evaluation process.

PART Annual Measures: Percentage of Planned Outputs Delivered in Support of HHRA

Annual measure calculation: This measure is calculated by tracking the completion of IRIS assessments each year, which includes the number of IRIS assessments submitted for interagency review or external peer review. Note that completion of all of these assessments comprises a single APM, and this measure does not track all APMs under the LTG like measures for other ORD programs often do.

The development of outputs from the IRIS program includes developing IRIS assessments in a multi-year process in which EPA is working on assessments of 75 to 80 chemicals. The table below lists the chemicals planned for assessment in FY 2006-2008 and the delivered outputs for FY 2006 and 2007. In FY 2006 and FY 2007, the HHRA program delivered 100% or all 16 of the assessments both years.

PART Measure for LTG 1: Number of IRIS assessments submitted for interagency review or external peer review

2006 (100%)	2007 (100%)	2008 (TBD)
16 delivered outputs	16 delivered outputs	___ delivered outputs
16 planned outputs	16 planned outputs	16 planned outputs

Perchloroethylene	Bromobenzene	Cerium	Trichloroacetic acid
Dibutyl phthalate	Nitrobenzene	Acrylamide	Propionaldehyde
tetra-PBDE		EGBE	Carbon tetrachloride
penta-PBDE		2-Hexane	Tetrahydrofuran
hexa-PBDE		Kepone	cis-1,2-DCE
deca-PBDE		Thallium	trans-1,2-DCE
Ethylene Oxide		Mirex	pentachlorophenol
HCCPD (less than life time)		Beryllium	1,2,3-Trichlropropane
Acrolein (less than life time)			
Ethylene Oxide (less than life time)			
Phosgene (less than life time)			
Hydrogen Sulfide (less than life time)			
Trimethylpentane			
1,1,1-trichloroethane			

During the PART process, it was agreed that completing assessments for review was the appropriate annual measure of performance pertaining to LTG 1, because Interagency review is not under the control of EPA. Issuing final assessments also was important from a long-term perspective. Therefore, the FY 2008 Congressional Justification includes the annual performance goal of posting eight finalized assessments on the Internet. The resulting impact of new and revised final assessments will be captured in the data for the long-term outcome measure listed below examining use in records of decision (ROD).

LTG 2: State-of-the-Science Risk Assessment Models, Methods, and Guidance

Long-term measure: none (captured by measure for LTG 1)

Annual measure: Percentage of planned outputs delivered in support of HHRA Technical Support Documents

Annual measure calculation: This measure is calculated by tracking the completion of all APMs under LTG 2.

During the PART process, it was agreed that the long-term outcome of LTG 2 is best measured by the quality and impact of the assessments that are completed under LTG 1 to inform decision-making. However, the annual progress of work under LTG 2 is measured by the completion of APMs. ORD is currently compiling end-of-year data on the completion of APMs for FY 2007 (unofficial % completion included below). For FY 2006, while performance was previously reported as 100%, a recent review indicated a data entry error; the correct total should have been reported as 83% or 5 of 6 HHRA APMs complete. APM 357 listed in the MYP was completed a year late (the 2 FY 2006 APMs under APG 8 are not part of the calculation as they belong to the Risk Assessment Forum, for which all subsequent APMs were removed from the HHRA MYP beginning in FY 2007). ORD plans to work with OMB to correct the FY 2006 data error during the Fall Update for PARTweb.

LTG 3: Integrated Science Assessments (formerly AQCDs)

Annual measure: Percentage of planned outputs delivered in support of Air Quality Criteria/Science Assessment documents

Annual measure calculation: This measure is calculated by tracking the completion of all milestones under LTG 3. These milestones are captured in the APMs, but do not always correlate 1:1 with the APMs because some milestones are considered interim steps toward broader APM outputs. For example, the 2nd external review drafts (ERD 2) are considered milestones toward the final assessment rather than an APM of their own.

The table below lists the individual Integrated Science Assessment milestones tracked for FY 2006-2008. In FY 2006, one milestone was delayed, the CO AQCD*. Litigation on NOx and SOx required earlier completion of these assessments and resulted in a shift of resources and delay in the CO AQCD. In FY 2007, the HHRA program completed 100% of the milestones. In FY 2008, HHRA has 4 APMs but 5 milestones given the NOx & SOx eco (ERD 2).

LTG 3—Integrated Science Assessments:

2006 (80% milestones met)	2007 (100% milestones met)	2008 (TBD)
4 delivered outputs	3 delivered outputs	___ delivered outputs
5 planned outputs	3 planned outputs	5 planned outputs
Ozone (ERD)		PM (ERD 1)
Ozone (final)		
Lead (ERD 1)	Lead (final)	
Lead (ERD 2)	NOx health (ERD 1)	NOx health (final)
CO (integrated plan)*	SOx health (ERD 1)	SOx health (final)
		NOx & SOx eco (ERD 1)
NOx & SOx eco (ERD 2)		

Summary of Percent Completion of PART Annual Measures for HHRA

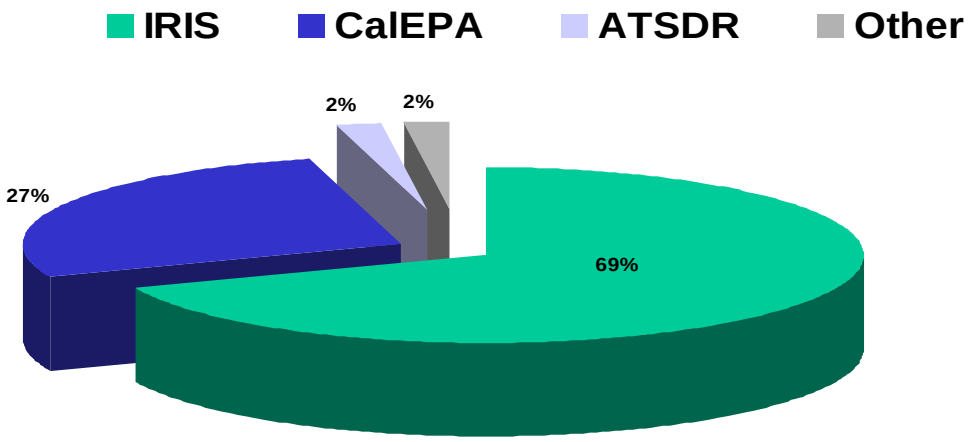
	LTG 1[1]	LTG 2[2]	LTG 3[3]
FY 2004	48%	83%	0%[4]
FY 2005	80%	44%	100%
FY 2006	100%	83%	100%
FY 2007	100%	100%	100%

Percentage of Regulatory Decisions in Which Decision-Makers Used HHRA Peer-Reviewed Health Assessments

Long-term measure calculation: This measure is calculated by reviewing regulatory and records of decisions (ROD) made by EPA program offices in recent years, determining how many quantitative health assessment values were used in these EPA program decisions and what percentage of these values had been developed by the HHRA Program. There were two major aspects to the 2005 analysis of extent of use of IRIS values in the agency programs RODs that formed the basis for this long-term measure. The first was the review of the Agency's Office of Air and Radiation (OAR) RODs for the National Air Toxics Assessment (NATA) and the second was the review of RODs for representative hazardous waste sites on the National Priorities List (NPL). Source: RAGS D Toxicity Tables provided by OSWER Site Managers.

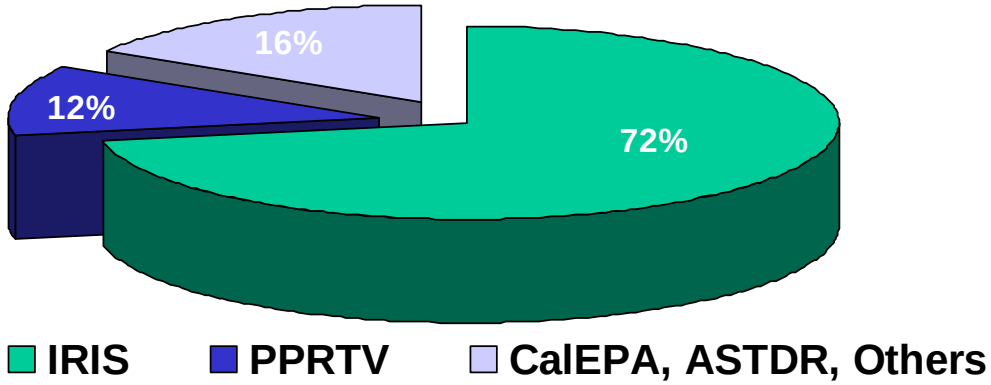
[1] Includes HHRA health assessments
[2] Includes HHRA technical support documents
[3] Includes HHRA AQCD documents
[4]The only LTG 3 APM was the final Ozone AQCD which was delayed in agreement with OAR to help meet a higher priority court-ordered deadline to complete the Particulate Matter AQCD.

Of 135 chemicals and compounds used in NATA, 69% rely on IRIS values. These values helped identify chemicals that contribute to health risks.



HHRA toxicity values are used in baseline and screening level assessments at the beginning of the Superfund process.

The HHRA Program provides health information on 84% of chemicals identified at ten representative hazardous waste sites on the National Priorities List (NPL).



<u>Long-Term Measure for PART: Percentage of Regulatory Decisions in Which Decision-Makers Used HHRA Peer-Reviewed Health Assessments</u>

Further analysis of RODs from 53 NPL sites indicated the types of health information and values that may be needed for site specific assessments. After screening assessment, the sites averaged 42 chemicals of concern per site. On average, 134 toxicity values were available for evaluation at these sites. These 134 values include some combination of oral/inhalation, cancer/noncancer, and chronic/subchronic estimates to facilitate a complete assessment of soil, water and air

exposures. The percentage of "values available" relative to the "number of possible evaluations" is the basis for the following baselines.

Calculation of measure: This long-term measure is calculated by dividing the number of toxicity values available from the HHRA program by the total number of evaluations identified as needed for these NPL sites.

This baseline of 44% is based upon only IRIS values and does not reflect inclusion of PPRTV. These percentages reflect the fact that many needed toxicity values are not available from any source because the data are unavailable to support a quantitative assessment. While IRIS and PPRTV assessments are available for over 80% of chemicals assessed at some Superfund sites, the actual percentage of values needed may be closer to 40-50% because of lack of data available to support quantitative assessment.

	2005 Actual	2008 Target	2010 Target
Percentage of coverage of all possible evaluations in which decision-makers used IRIS-HHRA peer-reviewed health assessments in RODs for NPL sites.	44	48	52

Long-Term Outcomes

As part of its review, the BOSC will provide ratings of the program's progress toward each long-term goal.

	2007 Baseline	2010 Target
Rating of the appropriateness, quality, and use of ORD science under LTG 1.	TBD by BOSC	TBD
Rating of the appropriateness, quality, and use of ORD science under LTG 2.	TBD by BOSC	TBD
Rating of the appropriateness, quality, and use of ORD science under LTG 3.	TBD by BOSC	TBD

The HHRA program's performance measures are based on the LTGs and annual milestones (APMs and APGs) in the most recent MYP. The long term performance (PART) measure listed below reflects work being done in the HHRA program that corresponds to LTG1.